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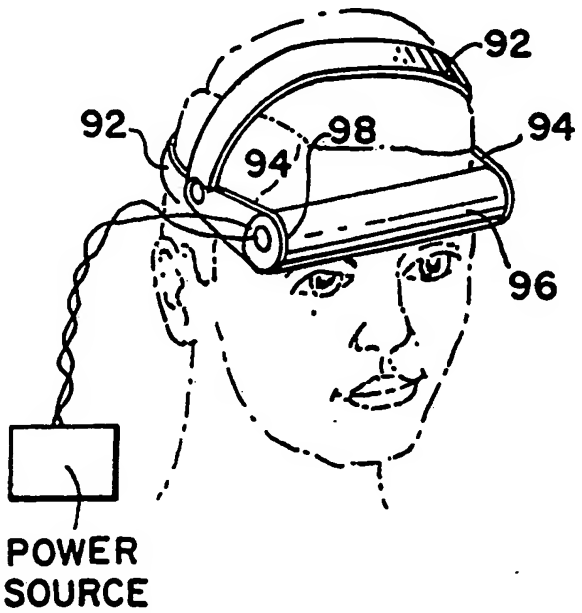

(57) Abstract

Phototherapy for the treatment of seasonal affective disorder (SAD) and analogous problems is carried out by a portable device for mounting on the head of the patient such as in the form of a hat, visor, headband (92) or helmet-like structure or spectacle frames or the like, and including a light projecting device such as a fiber-optic device or an incandescent or fluorescent light bulb (98) supported thereby close to the patient's eyes.

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PORTABLE LIGHT DOSAGE SYSTEM

The present invention relates to improvements in phototherapy especially for the alleviation of winter depression and similar syndromes; and, more particularly, to a convenient device for phototherapy.

Phototherapy is known especially for the treatment of winter depression, the "winter blues" and other light responsive psychological and psychiatric conditions. Considerable research conducted over the last several years on the effects of phototherapy on the above-identified conditions have shown a definite positive result.

In brief summary, it has been discovered that sunlight and bright artificial light can suppress human melatonin secretion; that patients with seasonal mood cycle winter depression improved when hours of daylight were lengthened with bright artificial light; that depression, hypersomnia, overeating and carbohydrate craving were reduced with phototherapy; that bright light has a marked antidepressant effect whereas dim light does not; that seasonal affective disorder (SAD) is reduced by phototherapy with the results of reduced irritability, reduced fatigue, reduced sadness and improved sleep; that exposure from 2 to 6 hours per day of light at 2500 lux reduces SAD and acts as an antidepressant; that phototherapy may aid in the treatment of bulimia and seasonal premenstrual syndrome.

Normal room light is insufficient, and even a brightly lit room provides a light intensity of only about 500 lux, insufficient to have any phototherapeutic effect. Previously, phototherapy for the above conditions has been effected by large cumbersome light emitting boxes which are not easily portable and which are inconvenient. The patient is effectively fixed to the equipment and cannot

proceed with other activities. As phototherapy at 2500 lux must be carried out for at least one hour per day, and preferably at least two to four hours per day to be effective, prior light emitting boxes have proven very inconvenient for the patient.

A large body of prior art exists which, while not directly pertinent to the treatment of SAD and related disorders, is of background interest for reasons which will be apparent below. Thus, miners' lamps are known which comprise a head mounted torch or flashlight for working in dark locales. In devices of this type, of course, the light is directed away from the eye rather than toward it.

The U.S. patent to Wyatt USP 4,360,253 relates to a safety glass mounted test result indicator including a small light emitting diode mounted on a spectacle frame. Of course, the degree of light provided by such an LED is far too low to be effective for the treatment of SAD, and also the light provided is not a steady beam of light for any significant length of time. Also see the U.S. patents to Rinard et al USP 4,145,122; Scrivo et al USP 4,086,004; Hamilton et al USP 4,044,756; and Harding et al USP 3,621,836, all of which are also unsuitable for the treatment of SAD and related disorders for reasons similar to those pointed out above.

The U.S. patents to Giannone USP 4,057,054 and Rehm USP 3,883,225 relate to eye treatment devices incorporated into or onto spectacle-like frames. These also are unsuitable for the treatment of SAD not only because of the absence of providing a steady beam of light at a sufficient intensity for a sufficient period of time, but also because such devices suffer from the same defects as the light boxes, i.e. they do not permit the patient to proceed with other activities during the treatment.

In a letter to the editor appearing in Vol. 43 (Feb. 1986) Arch. Gen. Psychiatry, by Mueller and Davies, the authors suggest treatment of SAD (referred to as seasonal energy syndrome) by the utilization of red-spectrum light in the fall-winter period as being superior to and more practical than full spectrum light, and this is suitably achieved by the use of rose colored glasses. The use of spectacle frames or the like as a supporting means for light projecting means for directing a steady stream of light into the eye of the patient is not suggested.

One of the major problems in administering light therapy is the inconvenience of having to be closed to a cumbersome and heavy light fixture. Although a device involving a few incandescent plant lights has been recommended for the treatment of SAD, there have been no previous reports of devices which are portable and worn or placed close to the eyes prior to the present invention.

It is, accordingly, an object of the invention to overcome deficiencies in the prior art, such as indicated above.

It is another object of the invention to provide for the more convenient treatment of SAD and related disorders.

It is still another object of the present invention to administer light in a convenient and portable way to individuals with winter depression, the "winter blues" and other light responsive psychological and psychiatric conditions, as well as to enhance immune function.

It is a further object to provide a device for shining light into an eye of a patient for the treatment of depression or the like.

It is still a further object of the invention to provide for the use of a head mounted lamp in the alleviation of sleep problems, depression, jet lag, winter blues, and to affect changes in the lymphocytes so as to affect the functional immune system.

According to the present invention, a device is provided offering advantages of portability and convenience in the treatment of disorders as mentioned above. The device is functional in various environments, including when the patient is ambulatory. The present invention allows the treatment to be accessible to more individuals and is more effective for those patients already using the old methods. Devices according to the present invention can be manufactured much less expensively than the prior light emitting boxes, because of the much smaller size and the smaller amount of light needed in view of its source being closer to the eyes. Small size involves not merely a reduction in size by downscaling, but provides the added advantages of being mounted on the user's head rather than resting on a nearby table or the like, thus ensuring that the light source is a fixed distance from the eyes and the flux to the eyes will be consistent.

The invention is achieved by mounting a suitable light source of sufficient power and capable of shining a steady beam of light into the user's eyes for a sufficient time, mounted on spectacle frames, a headband, hat or helmet-like support, with the light being directed toward the user's eyes to provide a therapeutic dosage of light.

The above and other objects and the nature and advantages of the instant invention will be more apparent from the following detailed description of several embodiments, taken in conjunction with the drawings wherein:

Fig. 1 is a schematic overall view of one possible embodiment of the present invention;

Fig. 2 is a schematic view of a second embodiment according to the present invention;

Fig. 3 is a more detailed, enlarged view consistent with, for example, the embodiment of Fig. 1;

Fig. 4 is a schematic perspective view of a detail consistent with the embodiment of Fig. 2;

Figs. 5 is a top view of a user's head wearing eyeglass frames consistent with the embodiment of Fig. 1;

Fig. 6 is an enlarged schematic front view of one eye showing various possibilities;

Figs. 7A, 7B and 7C are enlarged schematic views from above showing various possible arrangements in accordance with the invention;

Fig. 8 is a perspective view of an embodiment of the present invention showing another form of mounting means;

Fig. 9A is a schematic perspective view showing yet another embodiment in accordance with the present invention, and Fig. 9B is a schematic side view of the device of Fig. 9A;

Fig. 10 is a side view showing a variant in use;

Fig. 11 is a perspective view showing the device of Fig. 10; and

Figs. 12 and 13 are graphs showing test results produced by use of a device according to the present invention.

In general, the invention relates to the use of portable light-emitting elements held within a few inches of the subject's eyes by means of a cap, headband, helmet or the like, with the light being emitted or directed toward the eyes. The light-emitting elements may consist of light bulbs such as a fluorescent bulb or incandescent bulbs, or diffusing elements at the end of fiber optics or the like as exemplified in more detail below. Because the intensity of light incident on a surface is inversely

proportional to the square of the distance from that surface, it follows that a light source close to the eye (e.g. at most a few inches away) needs to be considerably less powerful than a light source which is some distance away.

Thus, when the light source is mounted on the head of the patient, the amount of light required to be emitted from the source needs only to be many times less intense than that required for equal phototherapy from a conventional light box placed at a distance approximately three feet from the patient.

The use of such a head mounted light source serves the purpose of alleviating and preventing a variety of psychological and physical conditions, including winter depression or SAD, a mild version of this condition known as "winter blues", premenstrual syndrome, jet lag, the physical and psychological discomfort associated with shift work, certain disorders of circadian rhythms such as delayed sleep phase syndrome, and certain infectious and inflammatory conditions which call for modulation of the immune system.

Fig. 1 shows a first construction according to the present invention including spectacles 10 which may or may not have lenses. A power source 12 and light source 14, similar to a standard battery operated flashlight, is worn on the user's belt. A fiber optic bundle 16 carries the light generated by the light source, which may be one or more light bulbs or a fluorescent bulb or the like, to the spectacles 10. On the front of the spectacle frames are provided diffusing and/or reflecting elements 18 which direct the light in a comfortable pattern towards the user's eyes.

The power source 12 may optionally include a battery charger and/or a plug connection 20 and line cord

for obtaining power from the mains, to replace and/or supplement the battery pack.

The placement of the diffusing and/or reflecting elements 18 is important and is described in more detail below in conjunction with Figs. 3-7.

In all cases it is important that the user's vision not be obstructed, particularly in the forward looking direction. On the other hand, it is also important that the power source and light source, functioning as light generating means, serve to generate a steady beam of light, preferably white or yellow light, at an intensity of at least 1000 lux, preferably at least 1500 lux, and that the power source be capable of maintaining such a steady beam of light for a period of at least about 0.5 hours, and preferably at least two hours per day, it being further understood that when the intensity is minimal, i.e. about 1000 lux, the term during which the steady light beam is applied must be maximal, i.e. about five hours in length.

Another important factor is the positioning of the light projecting means, and this is important for a number of reasons. As already mentioned above, intensity is inversely proportional to the square of the distance of the eye from the source, and therefore the light projecting means, e.g. the diffusing or reflecting means 18 or a fluorescent bulb, should be located as close to the eye as possible. On the other hand, the comfort of the patient is of considerable importance, and therefore the beam of light should be projected in a direction which provides the greatest comfort for the patient. As this may vary from patient to patient, it may also be desirable that suitable means for adjusting the distance and angle of the light projecting means be provided. For this same reason, it is also desirable to provide means for adjusting the intensity of the light.

Fig. 3 shows a number of possibilities for placement of diffusers or reflectors which may be used in conjunction with the embodiment of Fig. 1. The fiber bundle 16 is shown arriving at the spectacles frame at the rear, and splitting to serve an array of diffusing and/or reflecting elements disposed around the perimeter of the lenses as illustrated by positions A, B, C and D. For some patients it may be desirable to have diffusers or reflectors at plural positions, while for other patients one position may be sufficient.

Fig. 5 shows one example where the fiber bundle 16 splits behind the patient's head and where individual fibers 162, 164 and 166 terminate closely adjacent mirrors 163, 165 and 167, respectively, which reflect the beams of light exiting from the fiber ends toward the eye of the patient. Preferably the mirrors 163, 165 and 167 are diffuse reflective surfaces. Refractive elements can also be used.

Fig. 2 shows an alternative embodiment 40 in which the power source 42 is still worn on the belt or provided with a line cord. In this embodiment 40, however, the light source, which itself acts as the light projecting means, are light bulbs 48 mounted directly on the eyeglass frames, the electrical power passing through suitable wires 45.

The embodiment 40 of Fig. 2 also shows the use of an optional timer 50 and an optional transformer or rheostat 52 for adjusting power for control of light intensity. It will also be understood that a suitable timer 50 and/or a means 52 for adjusting the intensity of the beam of light can be used in any other embodiment, such as the embodiment 10 of Fig. 1.

Fig. 4 shows spectacle frames having light bulbs 48 powered through the wires 45 consistent with the embodiment of Fig. 2. Of course, the light bulbs 48 may

be placed in any desirable configuration which is most comfortable for the user, yet which will provide to the eyes a steady beam of light at an intensity of at least 1000 to 10,000 lux for a period of from five hours to about thirty minutes.

Fig. 6, which is a front view of an arrangement consistent with that shown in Fig. 3, illustrates a desired arrangement wherein the patient's forward viewing is not obstructed, but at most only peripheral vision. The various light projecting elements A, B, C and/or D may be diffusers, reflectors, refractors or actual light sources such as the light bulbs 48 of Fig. 4.

Fig. 7A shows a fiber bundle 16A having its end projecting a light beam against a reflector 18A which reflects the beam toward the eye. The reflector 18A is preferably adjustably mounted so that it can be moved toward and away from the eye and the end of the fiber and/or so that it can be rotated to adjust the angle at which the beam is reflected toward the eye.

Fig. 7B alternatively shows a refractively terminated fiber optic or naked fiber 16B having its end shaped so that the beam of light passed therethrough will strike the eye at a suitably effective, yet comfortable, angle. Means for adjusting the angle or distance from the eye of the end of the fiber is also preferably provided.

Fig. 7C schematically shows wires 45C leading to a bulb 48C for projecting a beam of light to the eye. In this case, an optional optical element 47 may be provided in the form of a screen, lens, reflector or parabolic mirror or the like.

Fig. 8 provides a schematic representation of a mounting or support means in the form of a hat or cap, bill, brim or visor 80, beneath which is mounted the light projecting means, e.g. a suitable fiber optic system as described above, or the combination light projecting means

and light generating means, e.g. one or more light bulbs either alone or with optional optical elements such as a screen, lens, reflector or parabolic mirror or the like, also as described above, or a fluorescent bulb. The bill, brim or visor 80 may be itself supported by a band 82 or made from part of a cap or hat. The bottom side of the visor or bill 80 is desirably made reflective. The mounting arrangement of Fig. 8 gives a reasonably satisfactory physiological orientation of delivered light, because the light comes from above as from the sun or sky.

Figs. 9A and 9B show a variant having a support means similar in nature to that provided by a welder's mask, and including a pair of supporting adjustable headbands 92 and a pair of adjustable visor arms 94 connected to the headbands 92 by suitable pivot connections 95 so that the visor arms can be rotated upwardly and downwardly in an arc about the pivots 95. The distal ends of the adjustable visor arms 94 in turn support a casing 96, preferably formed of plastic, and preferably provided with an internal reflector and housing therewithin a fluorescent bulb 98 which projects light downwardly toward the eyes.

Powering the fluorescent bulb 98 is a power source, which may be similar to that of a standard battery operated flashlight, and which may be worn on the user's belt. The power source may optionally include a battery charger and/or a plug connection and line cord for obtaining power from the mains, to replace and/or supplement the battery pack. Power from the power source is directed to the fluorescent bulb 98 by suitable wires. A switch is desirably provided on the power source to turn the bulb 98 on and off, and such switch may be a sliding variable resistance or "dimmer" switch to control the intensity of the emitted light. A second switch in the

nature of a timer switch may also be incorporated to set the length of time during which the light is on, so that after a given exposure the unit automatically turns off.

The embodiment of Figs. 10 and 11 is similar to that of Figs. 2 and 3, except that it also embodies a helmet-like support 110 which is curved so as to rest upon the front upper part of the head, with the fluorescent bulb 98 being suspended therefrom with suitable holders 112. Fig. 11 shows the front half of the fluorescent bulb 98 covered with a reflector 96 in the form of aluminum foil, although clearly any curved reflector can be used.

The embodiment of Figs. 10 and 11 has been successfully tested. Six patients each used a light helmet according to Figs. 10 and 11 for one week for two hours per day. Clinitians who were unaware of what treatment the patients were receiving rated their moods according to two standard rating scales, the Hamilton and the Supplementary Scores. According to the way in which the scales are measured, the higher the score the more severely depressed the individual. As shown in the graphs of Figs. 12 and 13, the average score at baseline (BL) was significantly higher than the score after one week of treatment (TX). Following one week of withdrawal (WD), patients relapsed to higher scores again.

The patients found the light helmet extremely comfortable and convenient. It did not obscure vision nor did patients complain of any side effects. The power of the fluorescent tube used was four watts.

As indicated above, the phototherapy delivering system of the present invention has considerable advantages over the previous devices used for delivering phototherapy, particularly in portability, convenience and patient comfort. The means for delivery of light to the eyes and the support means as disclosed are very convenient, simple, inexpensive and effective. The

overall system is capable of delivering 1000 to 10,000 lux of steady light to the patient's eyes for five hours to about 30 minutes per day, which is important, as is the requirement that such delivery of light be in a convenient and portable manner so that the patient can go about other business, and that the delivery be in a way which is not unpleasant to the patient.

It will be obvious to those skilled in the art that various changes may be made without departing from the scope of the invention. The invention is not to be considered limited to what is shown in the drawings and described in the specification, but only by the scope of the following claims.

WHAT IS CLAIMED IS:

1. A device for shining light into an eye for the treatment of depression or the like, comprising

support means for mounting on the head of a patient;

light projecting means, supported by said support means, for directing a steady beam of light into the eye of the patient; and

light generating means for generating said steady beam of light sufficient to reach the eye at an intensity of 1000 to 10,000 lux.

2. A device according to claim 1, wherein said light generating means comprises white light generating means.

3. A device according to claim 1, wherein said light generating means comprises means for generating light sufficient to reach the eye at an intensity of 1,500 - 5,000 lux.

4. A device according to claim 1, wherein said light generating means comprises means for generating sufficient light for about 2,500 lux to reach the eye.

5. A device according to claim 1, wherein said light projecting means comprises a fiber-optic bundle.

6. A device according to claim 1, wherein said light generating means and said light projecting means comprise a light bulb.

7. A device according to claim 1, further comprising timer means for maintaining said steady beam of light for a period in the range of 0.5 to 5 hours/day.

8. A device according to claim 1, further comprising means for adjusting the distance of said light projecting means from the eye.

9. A device in accordance with claim 1, further comprising means for adjusting the intensity of said beam of light.

10. A device in accordance with claim 1, further comprising means for adjusting the angle of said light projecting means relative to the eye.

11. A device in accordance with claim 1, wherein said support means comprises a spectacle's frame.

12. A device in accordance with claim 1, wherein said support means comprises a hat band.

13. A device in accordance with claim 1, wherein said support means comprises a head visor.

14. A device for shining light into an eye of a patient for the treatment of depression or the like according to claim 1, wherein said support means for mounting on the head of a patient comprises a head visor support means; and

said light projecting and light generating means comprises a fluorescent bulb.

15. A device according to claim 14, further comprising means for adjusting the distance of said fluorescent bulb from the eye.

16. A device in accordance with claim 14, wherein said head visor support means comprises a head visor with a reflective bottom surface.

17. A device in accordance with claim 14, wherein said head visor support means comprises a helmet-like curved support member for resting on the front upper part of the head.

18. A device according to claim 14, wherein said fluorescent bulb has a wattage of about four watts.

19. A method for the treatment and prevention of seasonal effective disorder, winter blues, premenstrual syndrome, jet lag, physical and psychological discomfort associated with shift work, disorders of circadian rhythms including delayed sleep phase syndrome and conditions requiring modulation of the immune system, comprising

treating a patient with phototherapy of 10,000-1,000 lux for 0.5 to five hours per day with a portable steady-light delivery system mounted on the head of the patient.

20. A process according to claim 14 comprising delivering steady white light to said patient at an intensity of 5000-1500 lux for at least one hour per day.

FIG. 1.

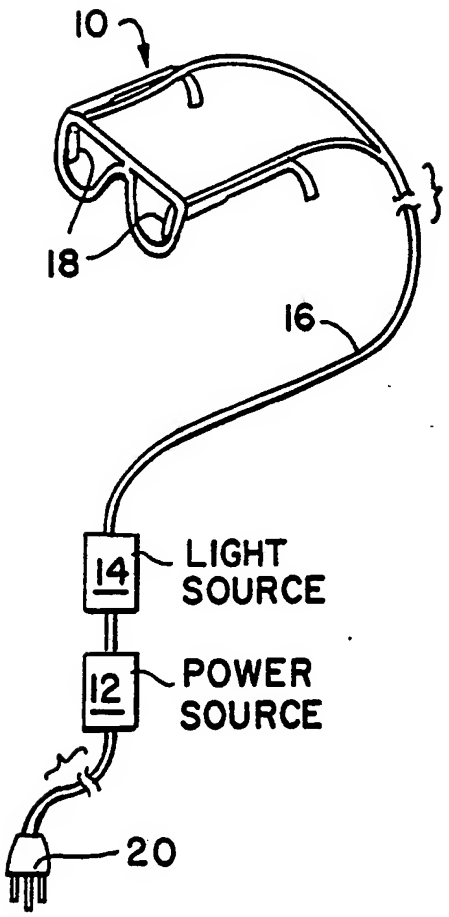


FIG. 2.

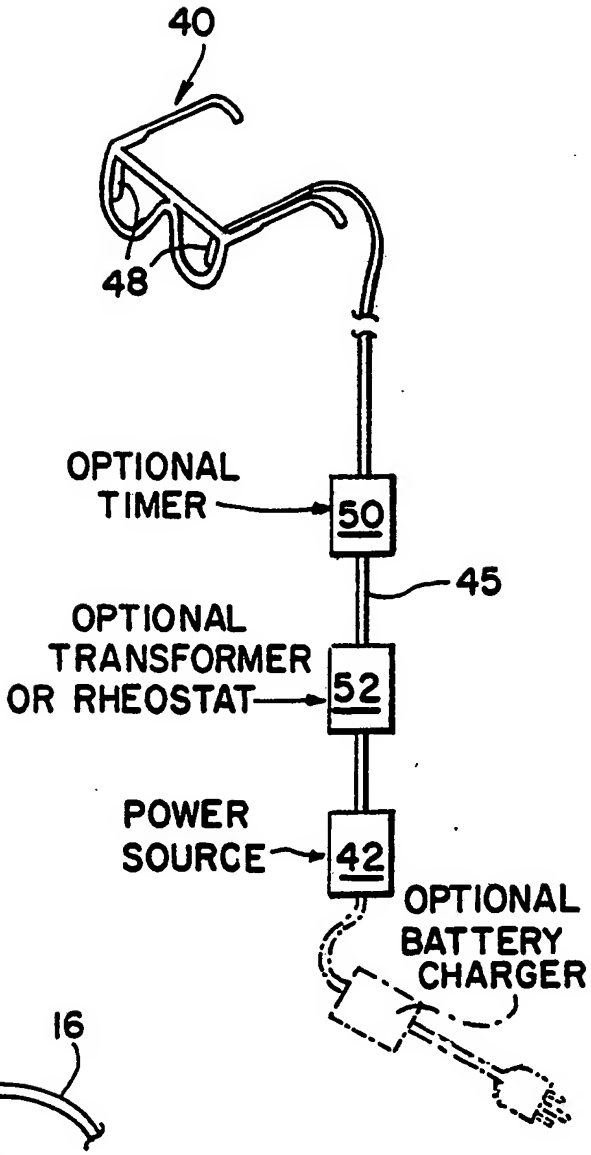


FIG. 3.

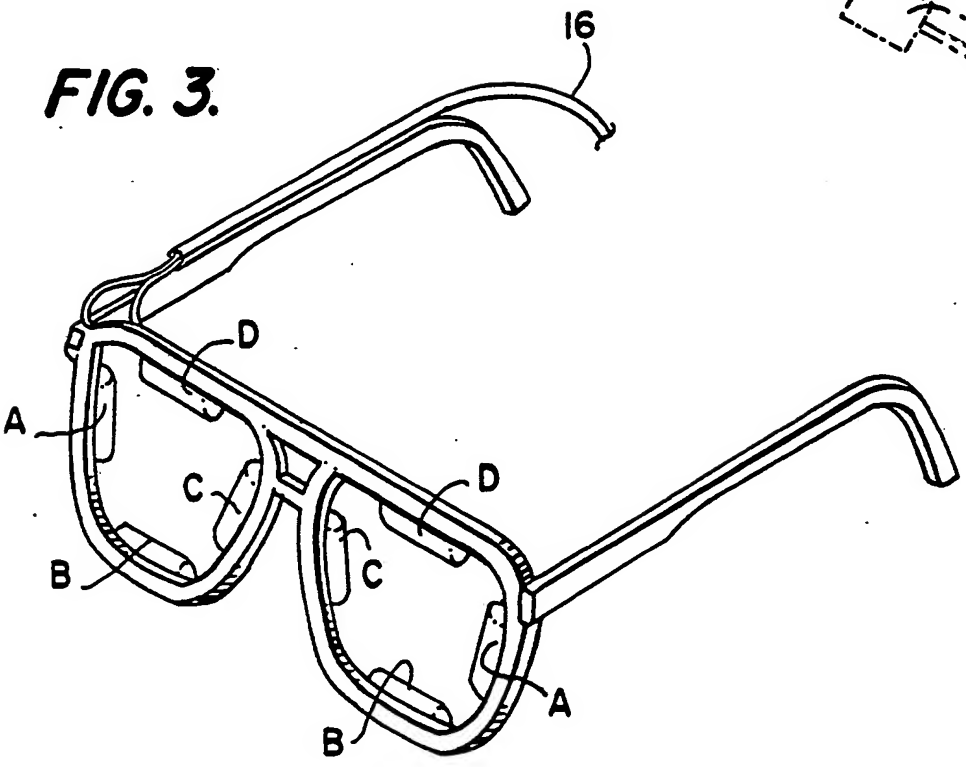


FIG. 4.

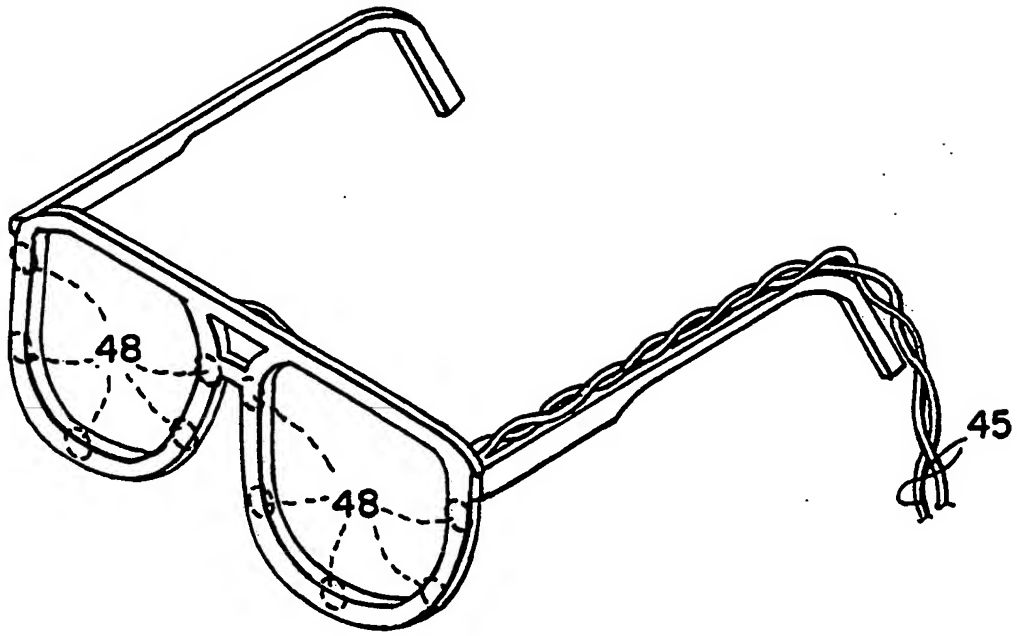


FIG. 5.

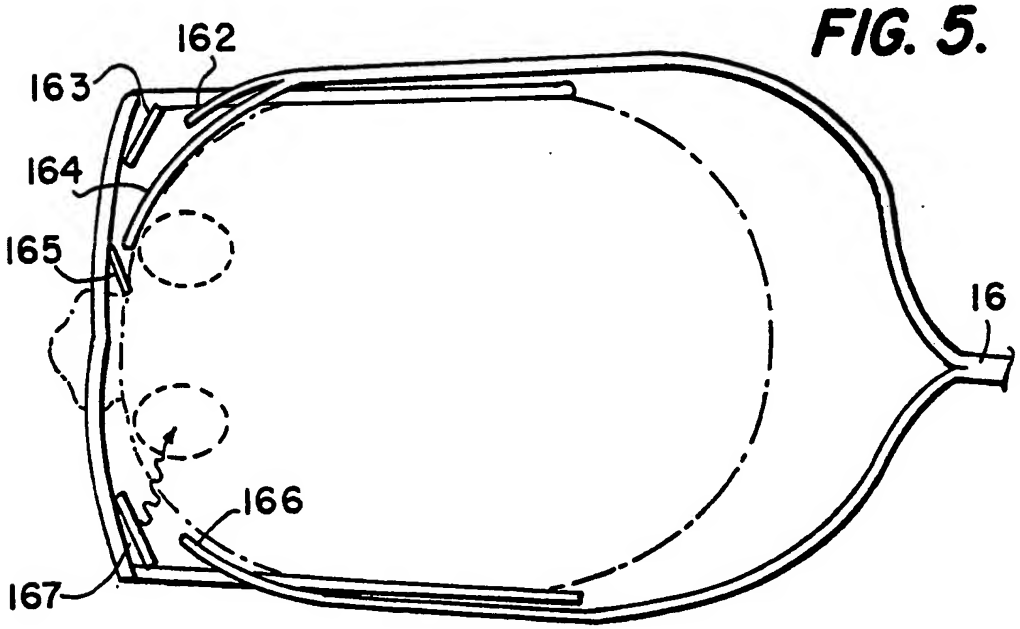


FIG. 6.

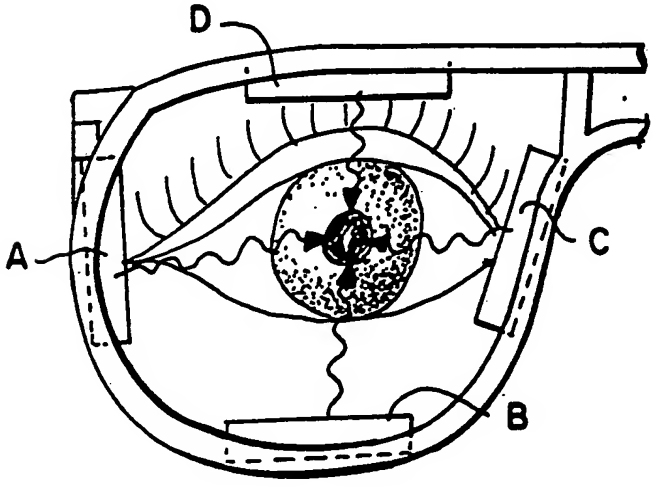


FIG. 7A.

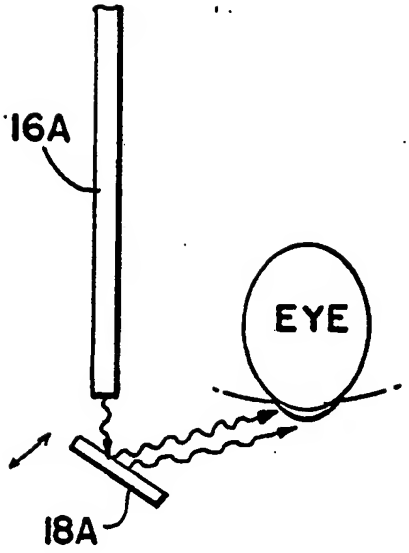


FIG. 7B.

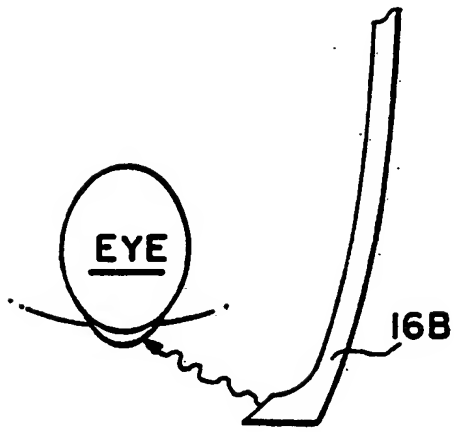


FIG. 8.

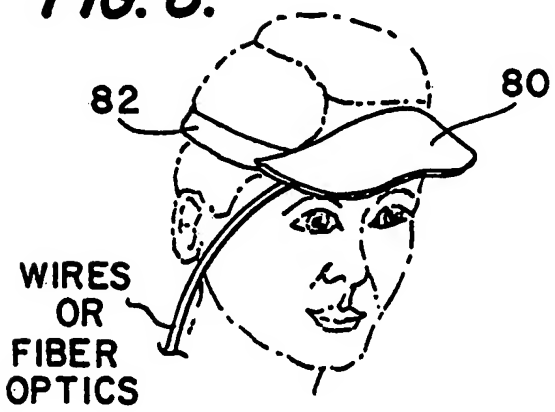


FIG. 7C.

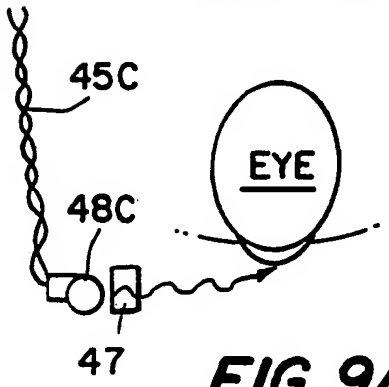


FIG. 9A.

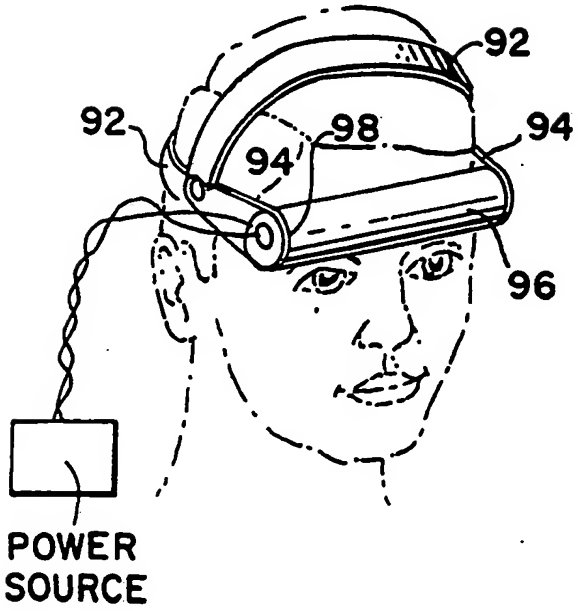


FIG. 9B.

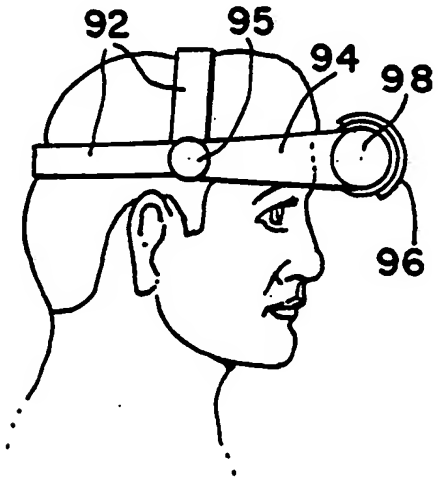


FIG. 10.

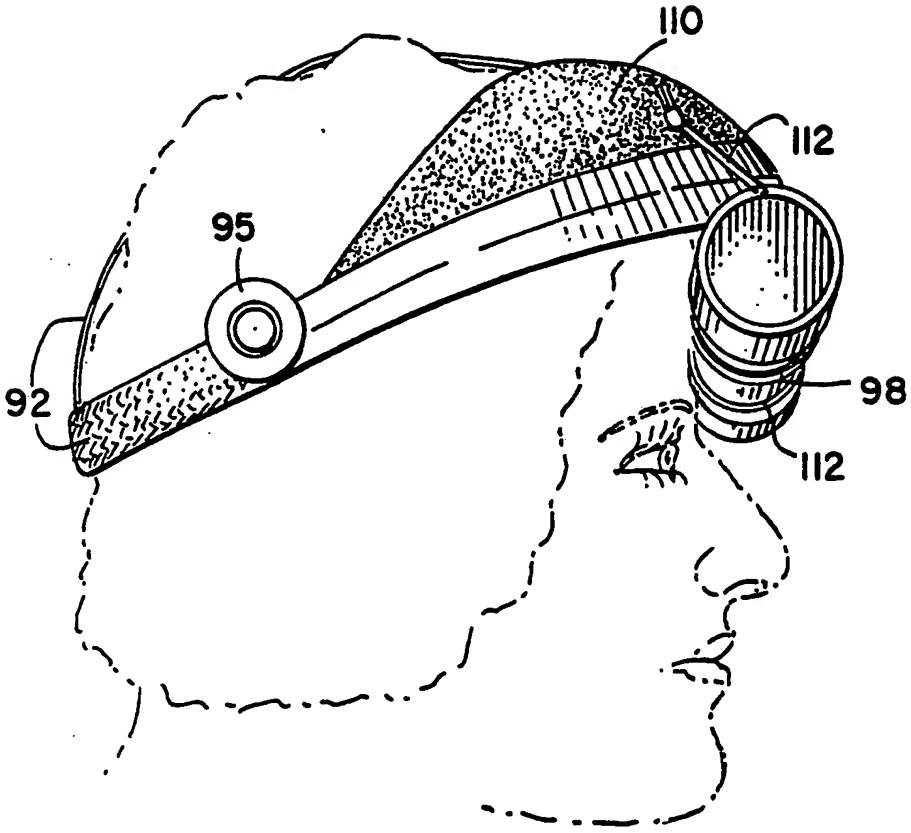


FIG. 11.

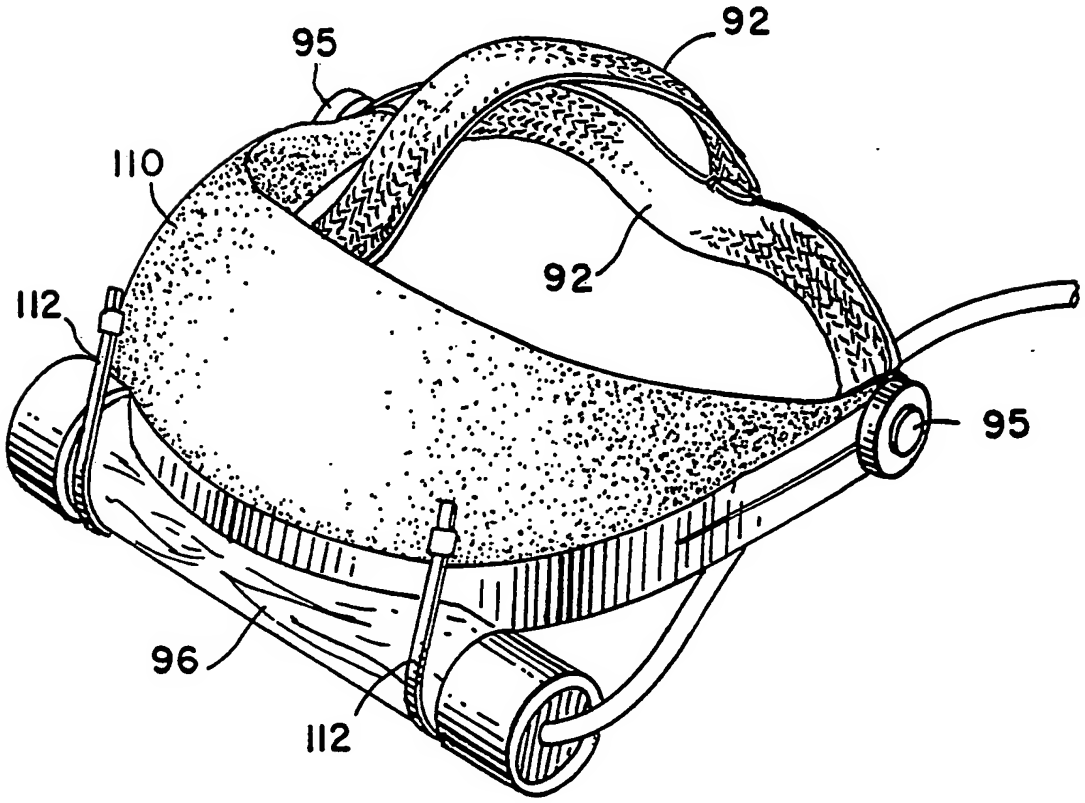


FIG. 12.

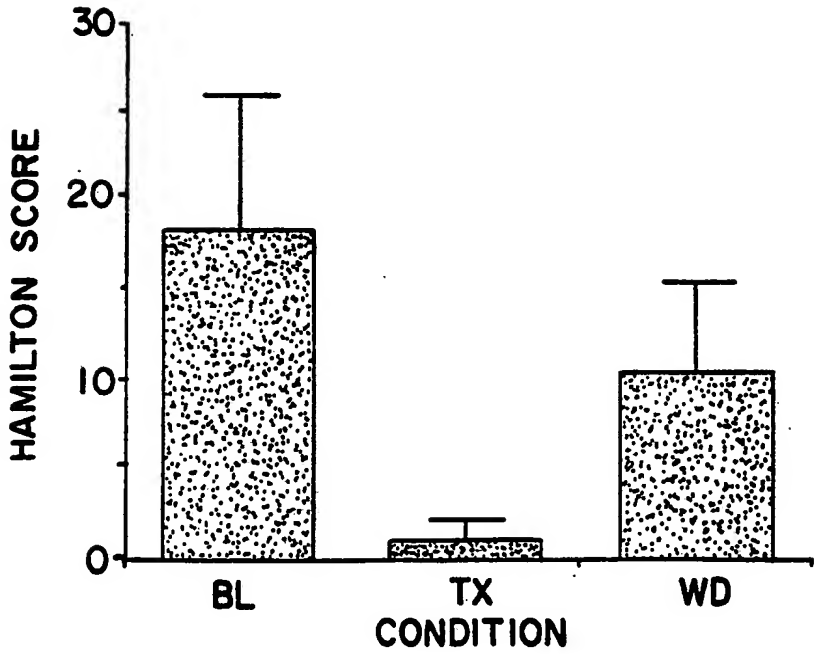
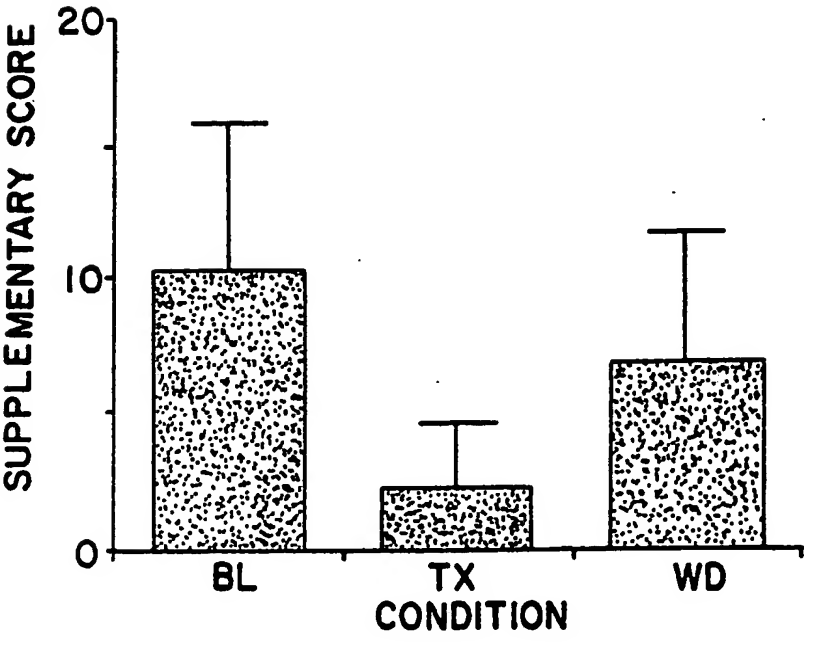

HAMILTON DEPRESSION RATING
HAMILTON SCORE
30
20
10
0
BL
TX
WD
CONDITION

FIG. 13.


SUPPLEMENTARY (ATYPICAL) SCORE
SUPPLEMENTARY SCORE
20
10
0
BL
TX
WD
CONDITION

INTERNATIONAL SEARCH REPORT

International Application No PCT/US89/01016

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(4) A61N 5/06
US. CL. 128/395

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/395,396,397,398,241,380,23,76.5

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	PHILLIPS, "Let the Sun Shine", 1985. The Chicago Tribune, 11 December 1985.	1-4,6,8,10-15,17, 19,20
Y	US,A, 4,057,054 (GIANNONE) 08 November 1977, See Fig. 1.	1-4,6,8,10,11, 19,20
Y	WIRZ-JUSTICE ET AL,; "Light Treatment of Seasonal Affective Disorder in Switzerland", 1986. Acta psychiatr. Scand. 1986: 74: 193-204.	1-4,6,8,10-15, 17,19,20
Y	US,A, 4,553,534 (STIEGLER) 19 NOVEMBER 1985, See Figs. 1,2.	1-4,6,8,10,12-15, 17,19,20
Y	US,A, 3,621,838 (HARDING ET. AL.) 23 November 1971, See Fig. 1,2.	1-4,6,8,10,11,19, 20
A	US,A, 4,608,978 (ROHR) 02 SEPTEMBER 1986, See Fig. 2,3.	5,7,9

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

28 April 1989

Date of Mailing of this International Search Report

12 JUL 1989

International Searching Authority

ISA/US

Signature of Authorized Officer

Mark S. Graham

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